# PALATIN

Palatin Technologies, Inc. NYSE American: PTN CORPORATE PRESENTATION June 2022

Carl Spana, Ph.D. President & CEO

Stephen T. Wills, CPA/MST CFO / COO

## **Forward Looking Statements**

The statements in this presentation that relate to future plans, events or performance are forward-looking statements, which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended. Such forward-looking statements involve significant risks and uncertainties, and actual results, events and performance may differ materially from those expressed or implied in this presentation. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following: (i) estimates of our expenses, future revenue and capital requirements; (ii) our ability to obtain additional funding on terms acceptable to us, or at all; (iii) our ability to advance product candidates into, and successfully complete, clinical trials; (iv) the initiation, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs; (v) the timing or likelihood of regulatory filings and approvals; (vi) our expectations on sales and market acceptance for bremelanotide (Vyleesi®) for hypoactive sexual desire disorder (HSDD), a type of female sexual dysfunction (FSD), including our licensees outside North America jurisdictions; (vii) our expectation regarding timelines for development of our other product candidates; (viii) the potential for commercialization of our other product candidates, if approved for commercial use; (ix) our ability and the ability of our licensees to compete with other products and technologies similar to our product candidates; (x) the ability of third party collaborators to timely carry out their duties under their agreements with us and our licensees; (xi) the ability of contract manufactures to perform their manufacturing activities in compliance with applicable regulations; (xii) our ability to recognize the potential value of our licensing arrangements with third parties; (xiii) the potential to achieve revenues from the sale of our product candidates; (xiv) our ability to maintain product liability insurance at a reasonable cost or in sufficient amounts, if at all; (xv) the retention of key management, employees and third-party contractors; (xvi) the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; (xvii) our compliance with federal and state laws and regulations; (xviii) the timing and costs associated with obtaining regulatory approval for our product candidates; (xix) the impact of legislative or regulatory healthcare reforms in the United States; and (xx) other risks disclosed in our SEC filings. The forward-looking statements in this presentation do not constitute guarantees of future performance. We undertake no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date of this presentation.



## **Company Profile**

Advancing a *novel mechanism* and approach to treating inflammatory & autoimmune diseases with a focus on ocular indications.



Demonstrated expertise moving programs from discovery to FDA approval.



Expertise in the biology and chemistry of the melanocortin system. First company to procure FDA approval for a melanocortin agent (Vyleesi<sup>®</sup>).



Strategy leverages our chemistry and biology across multiple therapeutic opportunities.

ľ	
L	

MOAs with the potential to modify underlying disease pathologies - not just treat symptoms.



# **Commercial Product and Development Programs**

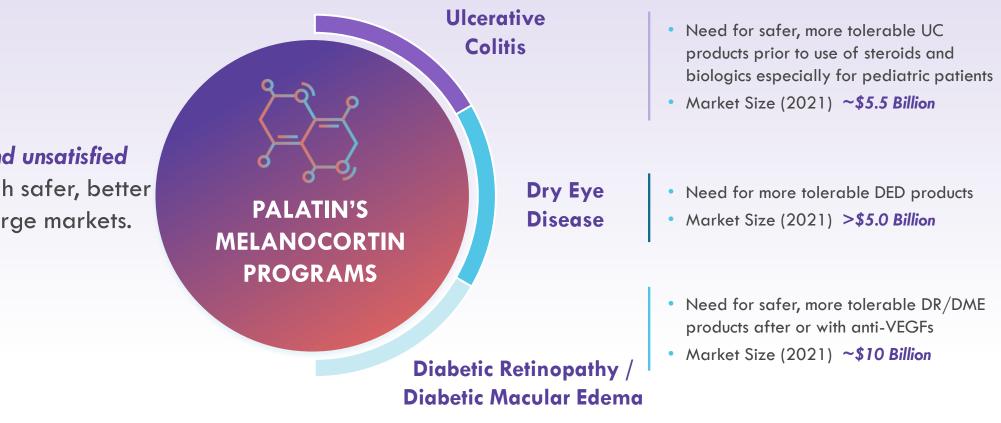
Commercial Product							
<b>Vyleesi<sup>®</sup> (bremelanotide)</b> Hypoactive Sexual Desire Disorder	FDA Approval 2Q2019						Seeking U.S. and ROW Licenses
Pipeline Development Programs							
Melanocortin Receptor Programs	Pre-clinical	Phase 1	Phase 2	Phase 3	NDA	FDA Approval	Status/Next Steps
<b>PL9643 MCr Agonist</b> Dry Eye Disease							Phase 2 & EOP2 Meeting Completed Phase 3 MELODY-1 Trial Initiated 4Q2021 Phase 3 Data Expected 2H2022
<b>Undisclosed MCr Agonist</b> Second Front of the Eye Indication							Finalize Indication Trial Initiation 2022
<b>PL9654 MCr Agonist</b> Diabetic Retinopathy							IVT Formulation Under Development
PL8177 Oral MC1r Agonist Ulcerative colitis (UC)							Phase 2 Trial Initiates 1H2022 with Data 1Q2023
Natriuretic Peptide Receptor Programs	Pre-clinical	Phase 1	Phase 2	Phase 3	NDA	FDA Approval	Status/Next Steps
PL3994 NPR-A Cardiovascular Disease							Phase 2a Trial Supported by American Heart Association
PL5028 NPR-A/C Agonist Cardiovascular and Fibrotic Diseases							Lead designated evaluating Options



## **Company Pipeline Valuation**

## Total Market Size of Palatin's Clinical Programs (2021) ~ \$20 Billion

Addressing **unmet and unsatisfied medical needs** through safer, better tolerated drugs in large markets.





# Target Milestones

Melanocortin System Inflammatory & Autoimmune Disease Programs	Date
PL9643 – Dry Eye	
Phase 3 Melody 1 Initiated	4Q2021
Phase 3 Melody-1 Interim Assessment	2H2022
Phase 3 Melody-1 <b>Data</b>	2H2022
PL8177 Oral – Ulcerative Colitis	
Phase 2 Proof-of-Concept Initiation	1H2022
Phase 2 Proof-of-Concept Interim data	2H2022
Phase 2 Proof-of-Concept <b>Data</b>	1Q2023
MCr Agonist (undisclosed) – 2 <sup>nd</sup> Front of Eye Indication	
Introduce indication	1H2022
PL9654 Diabetic Retinopathy	
IVT formulation preclinical data	1H2022
Natriuretic Peptide System Cardiovascular & Fibrosis Programs	
PL3994 – Heart Failure Preserved Ejection Fraction	
Open label Phase 2 Part-A <b>Data</b>	2H2021
Open label Phase 2 Part-B <b>Data</b>	2H2022
Vyleesi® (bremelanotide) for Hypoactive Sexual Desire Disorder	
North American rights regained	3Q2020
S. Korea licensee PK study Initiated	2H2021
S. Korea licensee PK study Data	2H2022
Re-license North American rights / additional ROW partnerships	2H2021-2022

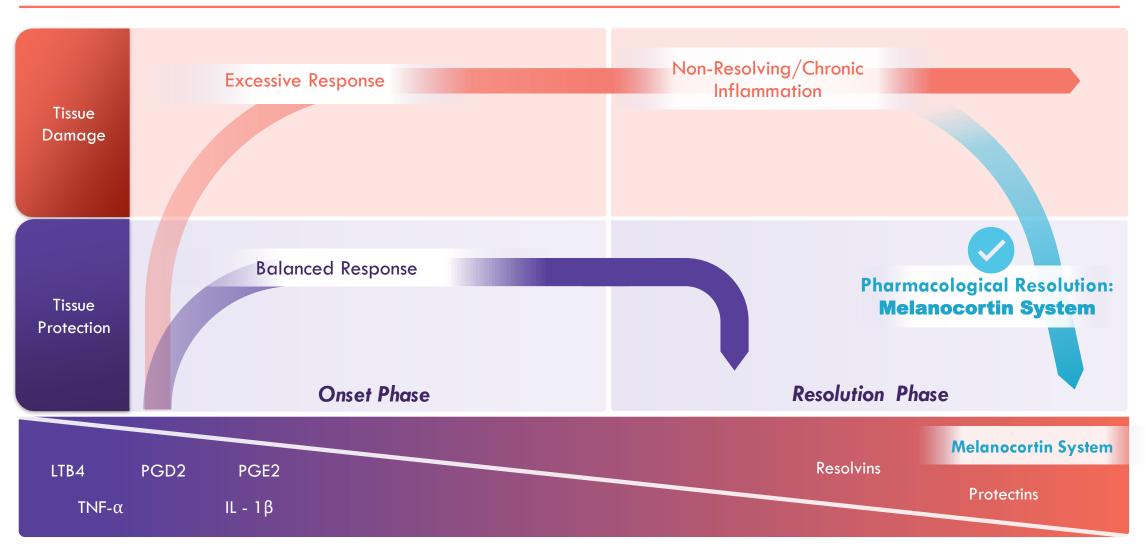


# Inflammatory & Autoimmune Disease Programs

Pioneering new ways to treat patients. Safely. Effectively.



# The Inflammatory Process in Health and Disease



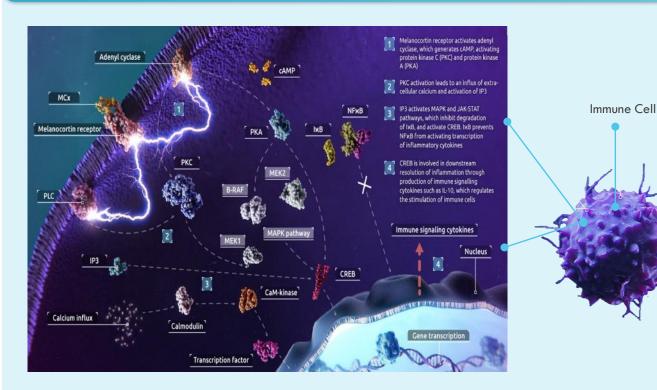
## PALATIN

Sugimoto MA, Sousa LP, Pinho V, Perretti M and Teixeira MM (2016) Resolution of Inflammation: What Controls Its Onset? Front. Immunol. 7:160.

8

## Mechanism of Action of Melanocortin Systems

### Mechanism of Melanocortin Signaling, Leading to Resolution of Inflammation



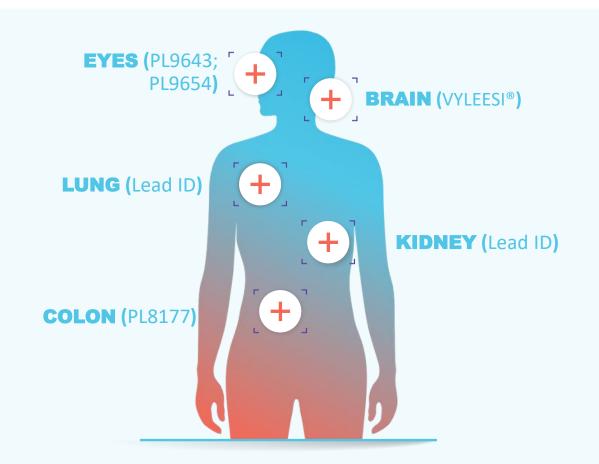
- Melanocortin system is up-regulated and integral to the resolution of inflammation and autoimmune pathologies
- Modulates the activity of cells of the immune system
- Activated during disease state
- Activates resolution of pro-inflammatory processes and promotes tissue healing
- MCr1 specific agonists have demonstrated in vivo activity in numerous disease models of inflammation



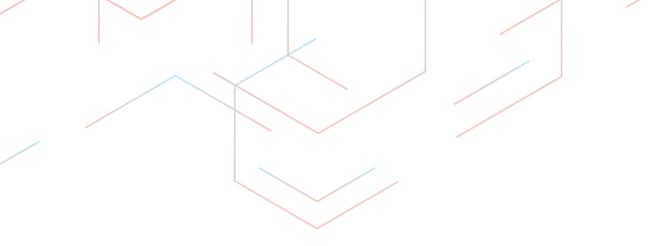
## Melanocortin Therapeutics Have Broad Utility

## Harnessing the melanocortin system in the body

Palatin's therapeutics work by *activating* endogenous melanocortin pathways to *resolve* damaging inflammation and promote tissue healing







# Ocular





# Ophthalmic Diseases with Unmet Medical Need: Front to Back

### Conjunctiva/Cornea/Ocular surface

• Dry eye

#### Cornea endothelium

- Protect donor corneas for transplantation
- Improve corneal transplant survival
- Protection of cornea with cataract surgery
- Fuchs Dystrophy

#### Iris/Ciliary Body/Choroid

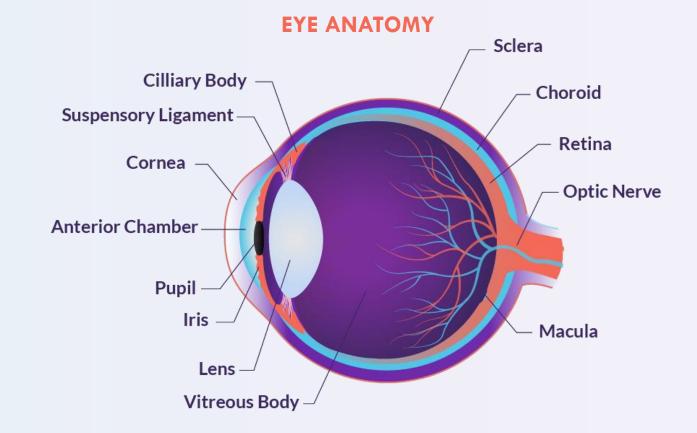
• Non-infectious uveitis

#### Retina

- Diabetic retinopathy
- Age-related macular degeneration

#### Optic nerve

Glaucoma





## Dry Eye Overview

Dry eye disease (DED) or **keratoconjunctivitis** is a multifactorial disorder of the tears and ocular surface

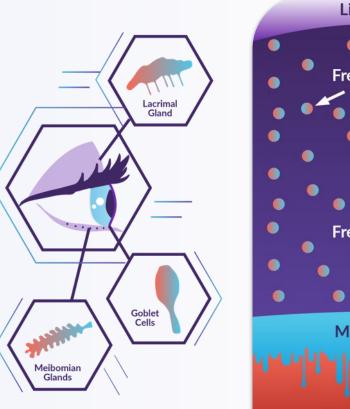
**Symptoms** include dryness, irritation, redness, discharge and blurred vision

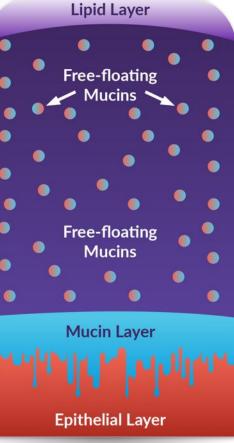
**Inflammation** plays a prominent role in the development and amplification of the signs and symptoms of DED

#### Current Treatments ~\$5 billion in revenue

- Restasis<sup>®</sup>-topical cyclosporin
- Xiidra<sup>®</sup>-topical integrin inhibitor
- Topical steroids
- Artificial tears

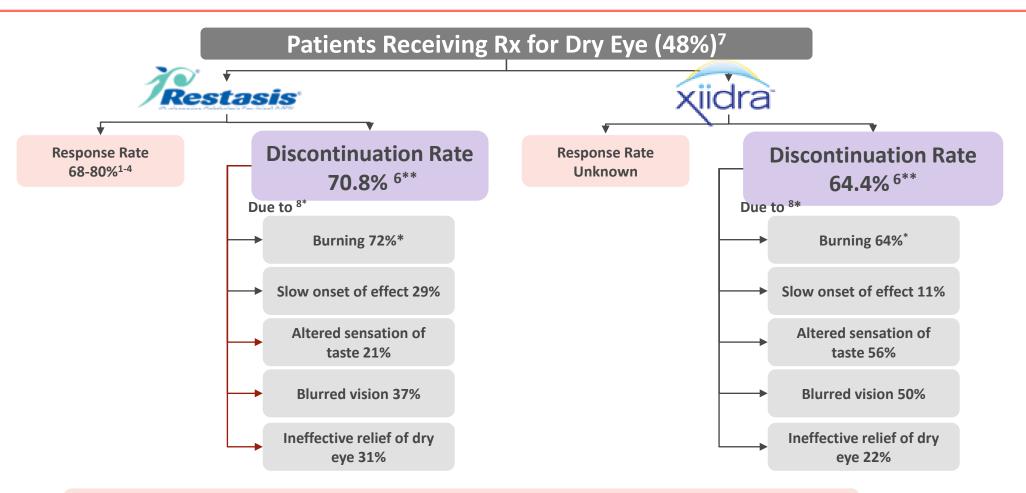
Current treatments have **efficacy and tolerability issues** and there remains a high medical need for new innovative treatments that affect underlying disease processes







# Compliance Remains an Issue with Current SOC Therapies *Poor tolerability leads to high discontinuation rates*



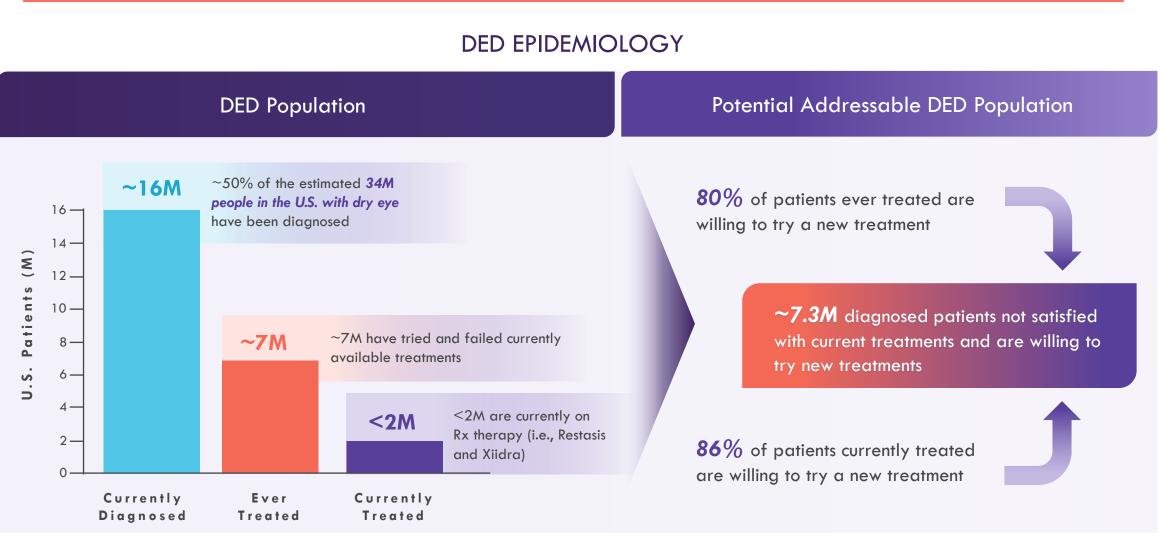
Side effects such as burning, blurry vision, and bad taste are main reasons for poor compliance, while lack of efficacy is also a main driver for discontinuation of Restasis

\*Note: Percentage value indicates the proportion of participants who experienced the side effect \*\* Note: Discontinuation rates within 12 months based on 2021 Real World study; side effects listed are not directly connected to discontinuation rate

Sources: 1. Sall K et al., (2000); 2. Schultz et al., (2014); 3. Torricelli et al., (2014); 4. Williamson et al., (2015); 5. Mah et al,. Clin Ophthalmol (2012); 6. White et al. Clin Ophthamol (2019); 7. Lum et al. Amer. Academy of Optometry (2018), 8. White et al. Clin Ophthalmol (2020)



## Approximately 16MM People Diagnosed with DED in U.S. An estimated ~7MM may be open to new treatment





# PL9643 DED Program Summary

PL9643 represents a *novel approach* to treating Dry Eye Disease (DED) by targeting the ability of the melanocortin system to resolve pathological inflammation and promote tissue healing

PL9643 base patent, if granted, runs at least to 2041

Phase 3 study **MELODY-1** initiated 4Q2021

PL9643 *treats inflammation* underlying the development and maintenance of DED, addressing both signs and symptoms of DED

Preclinical, DED studies PL9643 *significantly reduced* corneal epithelial damage with effects similar to Restasis<sup>®</sup>, a comparator reference agent

PL9643 **Dry Eye** Program



PL9643 Phase 2 DED study was the 1<sup>st</sup> evaluation of melanocortin agonist in ocular inflammatory indication

<u>}</u>

PL9643 is an *agonist* at the melanocortin 1 receptor (MC1r) and melanocortin 5 receptor (MC5r)



**Positive Phase 2 study** was exploratory with evaluations of multiple sign and symptom end points, patient segments, and time points;



Phase 3 registrational studies need statistical significance with a sign and symptom



16

## PL9643 Dry Eye Phase 2 Results



 $\mathcal{Q}_{\mathcal{A}}$ 

PL9643 demonstrated excellent ocular safety and tolerability

- No drug related serious adverse or adverse events
- No drug related discontinuations
- High ocular comfort



Differentiated & Favorable emerging product profile

• Rapid onset, excellent tolerability, safety and global efficacy

# Phase 2 Study - Signs Differences Between PL9643 and Vehicle

## Least squares mean change from baseline fluorescein staining in the moderate/severe subgroup (n=53)





# Phase 2 Study - Signs Differences Between PL9643 and Vehicle

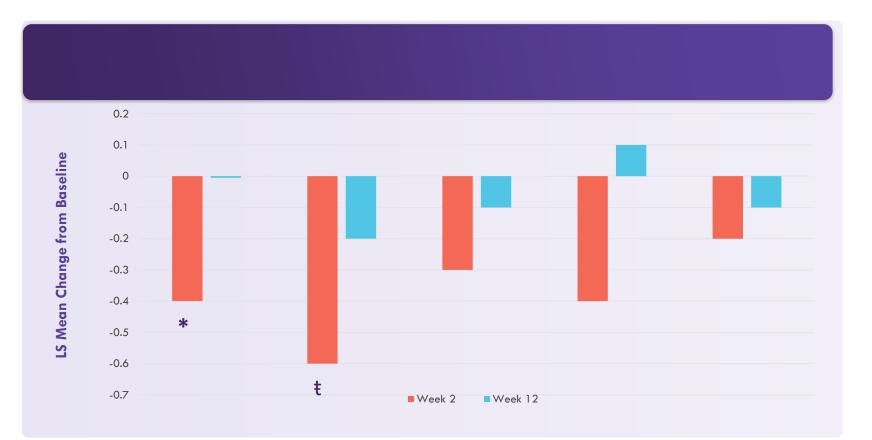
Least squares mean change from baseline conjunctival redness & tear film break-up time moderate/severe subgroup (n=53)



Signs of conjunctival redness showed *numeric improvements* (as demonstrated by negative change from baseline) and tear film break-up time showed significant improvement at 12 weeks

# Phase 2 Study – Symptoms Differences Between PL9643 and Vehicle

Least squares mean change from baseline Ora Calibra<sup>®</sup> Ocular Discomfort and 4-Symptom Questionnaire<sup>†</sup> scores in the moderate/severe subgroup (n=53)





20

# PL9643 Dry Eye Commercial Opportunity



#### **DIFFERENTIATED** Product

PL9643 has a favorable commercial product profile / Differentiating factors to current approved therapies

- Established method of treating dry eye (potent anti-inflammatory) but new mechanism of action
- Quick onset of efficacy
- Superior safety profile
- Superior patient tolerability
- Ideal profile for chronic use



#### UNMET MEDICAL NEEDS SPEED/SAFETY/TOLERABILITY

Current FDA approved treatments have high discontinuation rates due to high rates of side effects and slow onset of efficacy leading to patient and clinician dissatisfaction



#### LARGE MARKET OPPORTUNITY

DED is estimated to affect over 34 million people in the United States

- $\sim$ 16M people diagnosed with DED in U.S.
- ~7.3M diagnosed patients not satisfied with current treatments and are willing to try new treatments
- Rx market ~\$1.2b in 2021 and projected to be >\$1.6b in 2026

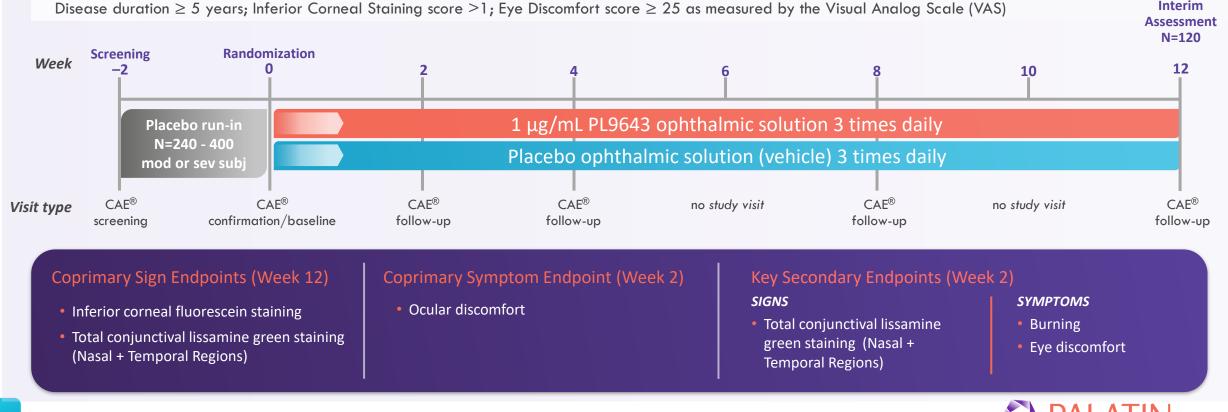


# Phase 3 Study Design and Primary Endpoints

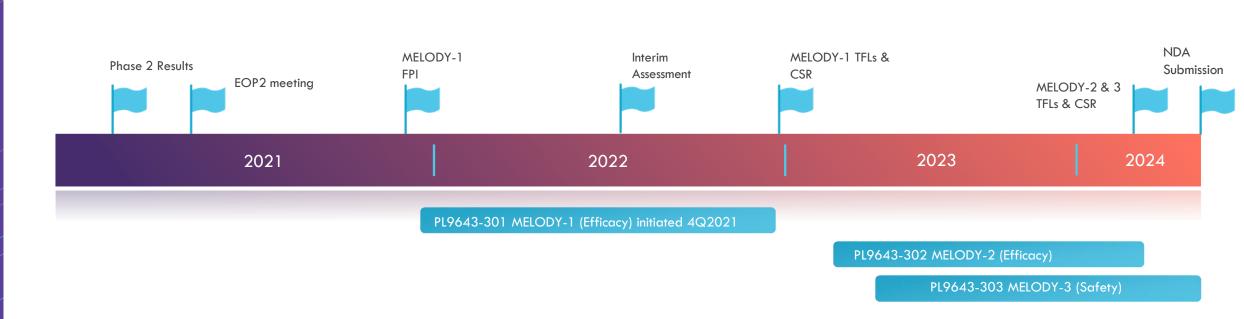
12-week, multicenter, 1:1 randomized, double-masked, vehicle-controlled adaptive design study

### Evaluate the efficacy and safety of PL9643 in up to 400 adults (initial target N=240) with moderate or severe dry eye disease defined as:

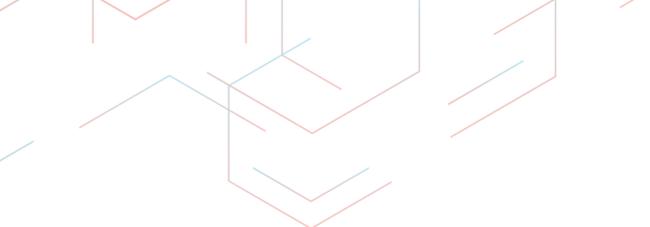
Interim



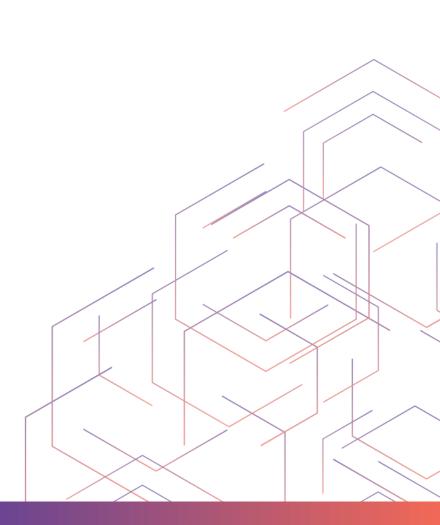
## PL9643 DED Program Timelines







# PL9654 for Retinal Diseases





## PL9654 for Retinal Disorders

The total retinal disorders drug market is valued at USD **\$20 billion** in 2021, and is projected to be **\$27 billion** by end of 2025; DR/DME estimated ~**\$10 billion** 

PL9654 is a *highly potent peptide* melanocortin receptor agonist with potential to dose less frequently (~3-6 months)

Why a Melanocortin Peptide for Retinal Disorders?

Market is seeking replacement for steroids without glaucoma or cataract side effects Retinal disorders such as diabetic retinopathy (DR), diabetic macular edema (DME), and AMD can *significantly impair vision* by damage to retinal tissue; *preservation of vision* is the key outcome for research

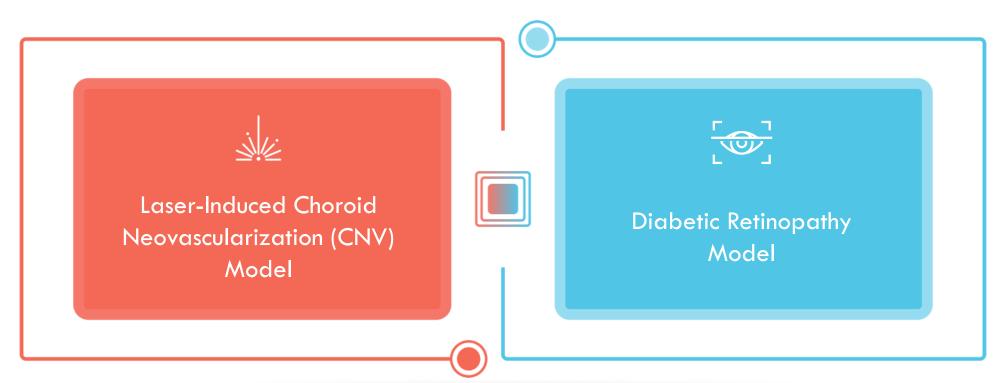
> High need for new products with enhanced safety and efficacy to delay progression, maintain and improve visual acuity, rescue treatment failures

PL9654 is **not systemically absorbed** allowing potential for excellent efficacy without safety concerns

Our melanocortin receptor agonists have been **evaluated in multiple animal models** of retinal disease where preservation of vision was demonstrated

## Preclinical Proof-of-Concept

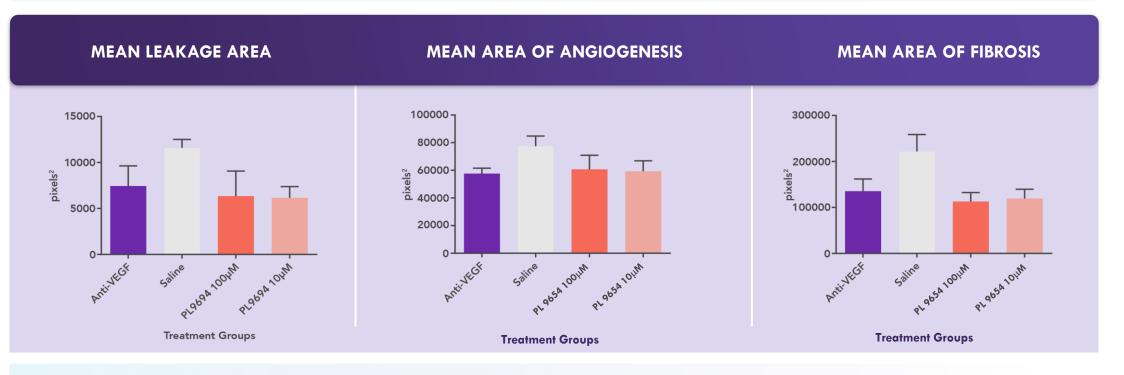
To **validate** melanocortin receptors as therapeutic targets for retinal vascular diseases, Palatin's melanocortin agonist compounds were tested in **two relevant animal models** 





# PL9654 Laser Induced Choroid Neovascularization Model

Model recapitulates main features of human age-related macular degeneration (AMD)



- PL9654 showed therapeutic activity comparable to anti-VEGF positive control
  - CNV leakage area reduced
  - Angiogenesis area reduced
  - Fibrosis area reduced (better than anti-VEGF)



## Diabetic Retinopathy Model

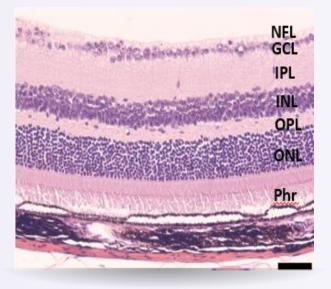
Melanocortin agonist demonstrated key indicators of *improve retinal health*, including:

Preserved retinal anatomy

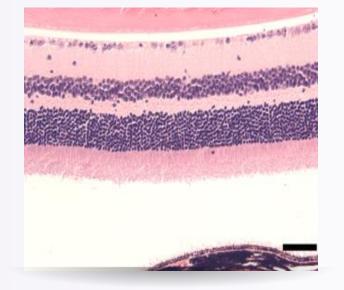
Suppressed pro-inflammatory cytokine to healthy control levels

Increased levels of IL-10, a marker of inflammation resolution

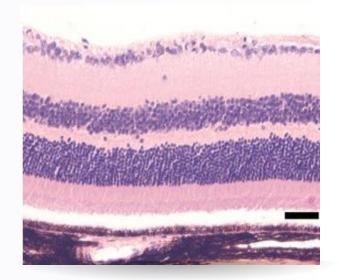
### **Healthy Control**



### **Diabetic; Untreated**

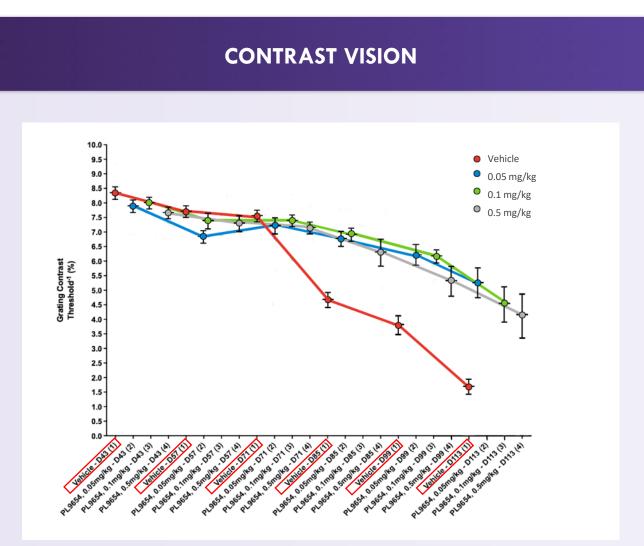


### Diabetic; melanocortin agonist



#### This rodent model develops diabetic retinopathy like that seen in humans

## PL9654 in a Rat Diabetic In-Life Retinopathy Model



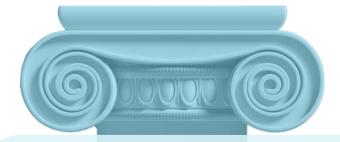
PL9654 **preserves contrast vision** as compared to controls

A second measure of visual acuity demonstrated *similar efficacy* to this measurement



## Retinopathy – Desired Target Product Profile to Determine Commercial Success

Efficacy



#### PL9654 was chosen based on:

- High potency at melanocortin receptors 1 & 5
  - Enables smaller needle, fewer AEs
- Demonstrated efficacy in preclinical animal models
- Enabling pharmacokinetics
- Desirable solubility profile
- Straight-forward synthesis path
- Excellent IP position

## **Pharmacokinetics (ROA)**



#### **PL9654 Ongoing Activities:**

- IVT sustained release formulation development (target is 3-6 months sustained dose)
- Additional preclinical models and measurements
- Genomic and proteomic characterization of treated animal models
- Extensive PK
- Toxicology studies

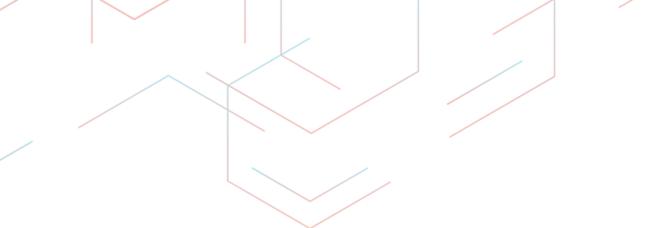
**Safety** 



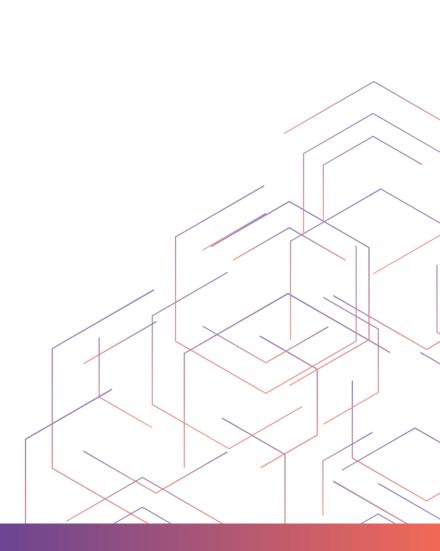
#### PL9654

- IND enabling studies and subsequent clinical studies are planned
- Minimal/No systemic exposure in preclinical studies

PL9654 IVT sustained release formulation meeting the program goals and positioned for IND submission in 2022



# PL8177 for Ulcerative Colitis





## PL8177 Oral Formulation for Ulcerative Colitis

Global ulcerative colitis (UC) market was valued at USD **\$5.5 billion** in 2021, and projected to be **\$8 billion** by 2026

Most treatments for UC are systemic and have **tolerability and safety limitations** 

PL8177 is a highly potent peptide and selective agonist at the MCr1

Why a Melanocortin Peptide for Ulcerative Colitis? MC1r is **found on epithelial cells** of the colon and is accessible from the lumen of the colon

Evidence from preclinical animal & human studies

PL8177-Oral and has demonstrated repeated robust, efficacy UC disease models

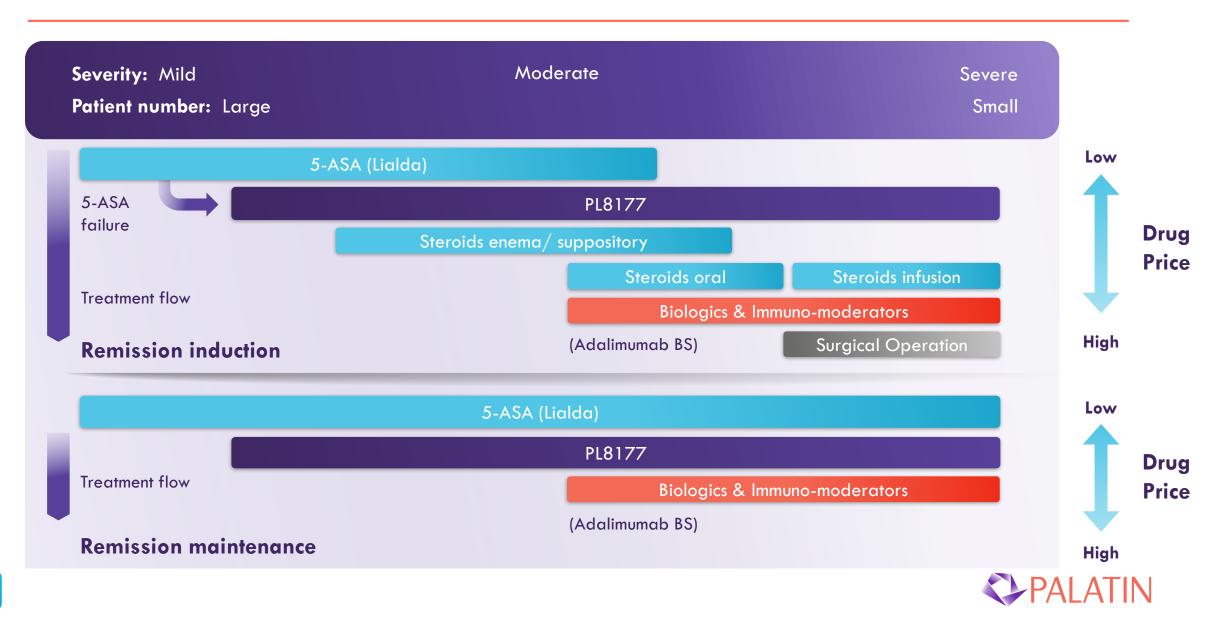
#### PL8177 is not systemically absorbed

- Potential for excellent efficacy without safety concerns
- Phase 1 SC SAD/MAD study no significant findings
- Oral Phase 1 study confirms colon delivery

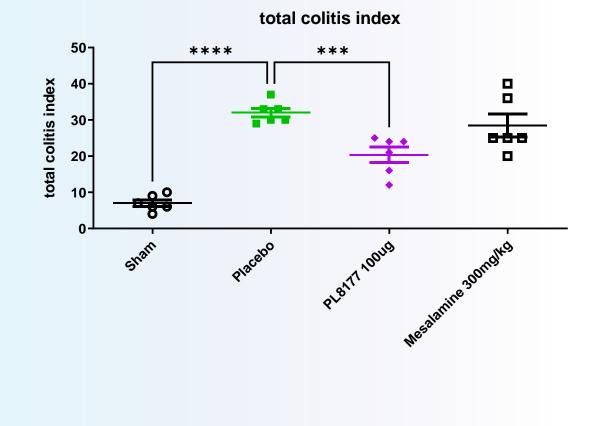
Currently available therapies cannot cure IBD, but many of them target various inflammatory pathways, resulting in more or less durable remission. However, these therapies come at a high price economically and physically, with potentially life-threatening side effects.

N. ENGL J MED 385:14 September 30, 2021

# Opportunity for PL8177 in UC Treatment Landscape



# PL8177 Pre-Clinical Histological Findings (Total Colitis Index in Rats)

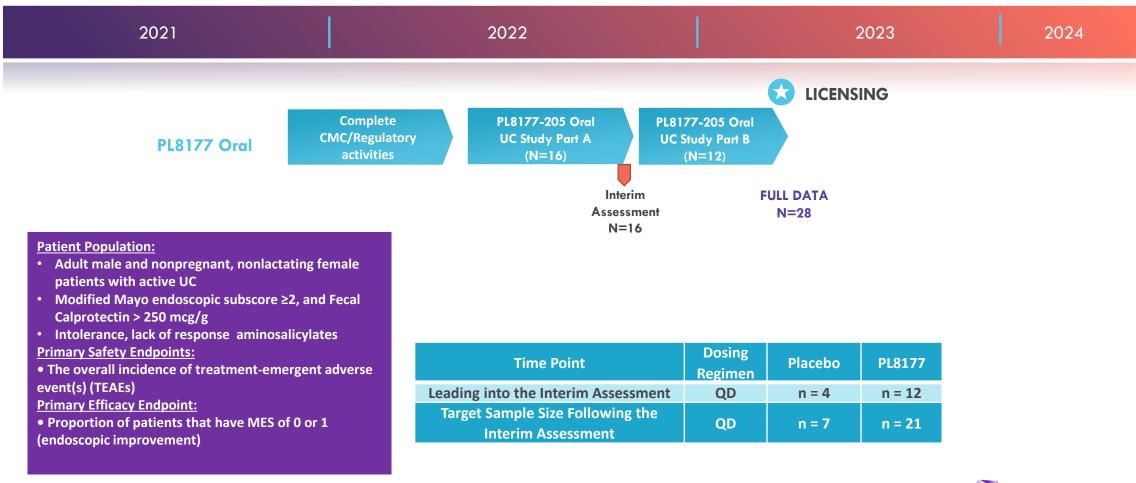


- The scoring was based on examining three sections from each colon per animal:
- Sections were taken at the distance of 2.5cm,
  5cm and 7.5cm from the anus
- Total colitis index includes observations
  - Abnormalities of mucosal architecture
  - Extent of inflammation
  - Erosion or ulceration
  - Epithelial regeneration
  - Percentage involvement by the disease process



# PL8177-205 Phase 2 Study Design & Timelines

### Phase 2 RCT parallel group study using an adaptive design to evaluate safety, tolerability and efficacy





## Ulcerative Colitis – Target Product Profile Needed for Commercial Success

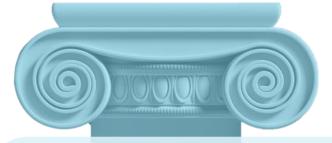




# PL8177 in animal models and Phase 2 planned:

- High potency at melanocortin receptors 1
- Multiple positive animal models proof of efficacy data in gold standard disease model
- Efficacy as good/better than 5-ASA and glucocorticoids in animal model data
- Phase 2 proof-of-concept trial initiation 1H2022 / Data 2H2022

## Pharmacokinetics (ROA)



#### PL8177 oral formulation PK:

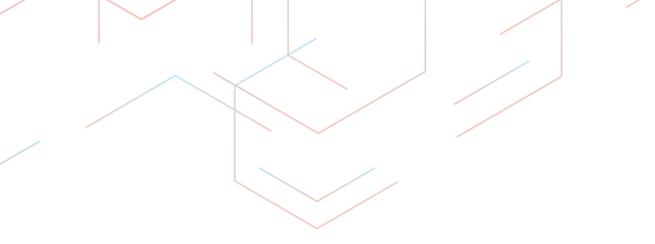
- Phase 1 radiolabeled micro-dose study with the oral formulation, confirmed colonic delivery of oral PL8177
- Orally dosed PL8177 remains in the colon there is no systemic exposure

## Safety

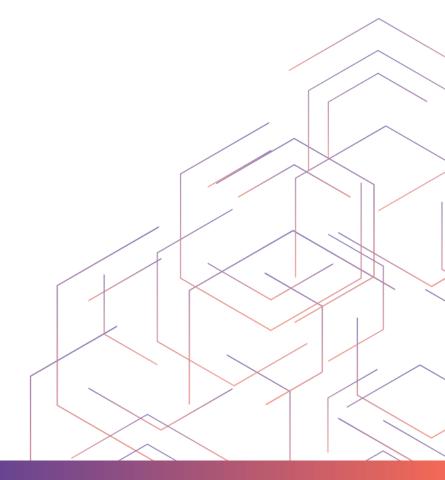


- Phase 1 clinical SAD/MAD study with the systemic formulation (SC) up to 3mg for 7 days, up to 5mg SC for a single dose
- No adverse events
- No toxicological findings in pre-clinical in doses
  >100-fold above planned clinical doses

PL8177 oral formulation meeting the program goals and positioned for success in Phase 2 POC



# Vyleesi®





# FDA Approved Vyleesi®

## Helping Premenopausal Women with Hypoactive Sexual Desire Disorder (HSDD)



# Hey, you. Meet Vyleesi. ...it's Now Approved

Vyleesi is the first and only as-needed\* treatment for premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD).





\*Administer subcutaneously as needed at least 45 minutes before anticipated sexual activity. The duration of its effect after each dose is unknown. Do not administer more than one dose within 24 hours or more than 8 doses per month.



# Vyleesi Operations/ Performance

## OBJECTIVE

Demonstrate the commercial value and upside of Vyleesi and re-license to a committed partner

### • Vyleesi is a valuable asset in the 'right" hands

• FDA approved product with limited competition

### FSD market

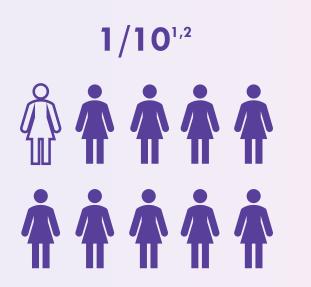
• Significant awareness needed / greater HCP and patient engagement

### • For the quarter ended March 31, 2022

- Gross product sales increased 67% over the prior quarter, decreased 27% over the comparable quarter in 2021
- Net product revenue increased 200% over the prior quarter, increased 144% over the comparable quarter in 2021
- Total prescriptions dispensed increased 20% over the prior quarter, flat compared to the comparable quarter in 2021.
- Refill rates, commercial insurance reimbursement, and net revenue per prescription dispensed increased over the prior quarter and comparable quarter in 2021
- Learn more about HSDD and Vyleesi at <u>www.vyleesi.com and www.vyleesipro.com</u>



# HSDD is a Significant Market Opportunity



Number of premenopausal women who have low desire with associated distress

Affects 5.8 million U.S. premenopausal women<sup>3</sup> (1 in 10 premenopausal women)<sup>1,2</sup>

98% (5.7M) of affected premenopausal

women not on therapy<sup>3</sup>

Focused on relevant digital channels

Creating an online community for HSDD patients

- Provide accurate information
- Tools to support the HSDD patient symptom check, speaking with your doctor and additional resources

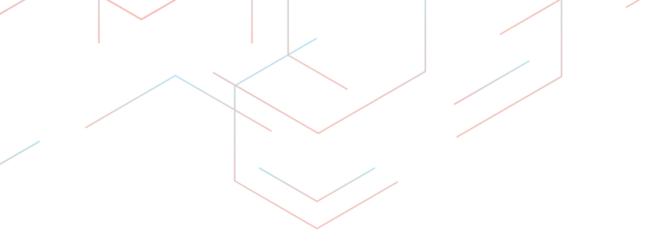
Ensure HCP readiness, provide information and tools to diagnose and treat HSDD patients with Vyleesi



<sup>1</sup> Shifren JL, Monz BU, Russo PA, Segreti A, Johannes CB. Sexual problems and distress in United States women: prevalence and correlates. Obstet Gynecol. 2008;112(5):970–978. <sup>2</sup> Goldstein I, Kim NN, Clayton AH, et al. Hypoactive sexual desire disorder: International Society for the Study of Women's Sexual Health (ISSWSH) expert consensus panel review. Mayo Clin Proc. 2017;92(1):114-128. <sup>3</sup> Palatin supported research that was performed by Burke, Inc., an ISO 20252–certified company, in compliance with the established standard for market, opinion, and social research.

# **Financial Snapshot**

Financial Highlights as of March 31, 2022					
Cash and Cash Equivalents	\$37.7 million				
Accounts Receivable	\$0.8 million				
Inventory	\$1.0 million				
Inventory Purchase Commitments (over the next 5 years)	\$9.0 million				
Summary Capitalization as of March 31, 2022					
	Common Shares and Equivalent				
Common Stock	231.7 million shares				
Preferred	0.1 million shares				
Options	21.7 million shares				
RSUs	13.0 million shares				
Fully Diluted Shares	266.5 million shares				



# Thank You.

